AMENDMENTS TO THE CLAIMS

The following represents the current status of all the claims submitted in the present application including changes made by this paper. It should be noted that the cancellation or withdrawal of claims in this application has been done without prejudice or disclaimer of any subject matter therein, the applicants reserving the right to pursue such subject matter in future continuing or divisional applications. By this paper, claims 1-4, 9, 13-15 and 18-19 have been amended.

Listing of claims:

1(currently amended): A method of optimizing the pacing mode and inter-site delay configuration of a dual chamber pacemaker of the type having means for sensing atrial depolarization events, means for sensing ventricular depolarization events and means for applying cardiac stimulating pulses selectively to the right, left or both ventricular chambers at a plurality of sites at predetermined delay intervals following detection of atrial depolarization events, said method comprising ~~the steps of~~:

(a) tracking a patient's intrinsic atrial depolarization events;

(b) measuring the patient's atrial cycle length (ACL) between successive atrial depolarization events over a first predetermined number of heart beats, N_1,

establishing a first set of inter-site delay intervals and storing the measured ACLs as an array in a memory to establish a baseline value wherein said inter-site delay intervals involve a plurality of sites in at least one cardiac chamber;

(c) changing at least one of one or more inter-site delay intervals and pacing mode configuration s for a second predetermined number of heart beats, N_2, less than the first predetermined number of heart beats by changing

(i) the delay interval of the pacemaker between successive sites from the baseline value to a different delay interval;

(d) measuring the patient's ACLs between successive atrial depolarization events over the second predetermined number of heart beats and storing the measuring ACLs in the array in said memory;

(e) calculating and storing an ACL feature value obtained from the patient's atrial cycle length measured in ~~steps~~ (b) and (d);

(f) repeating ~~steps~~ (a)-(e) in iterative cycles over a range of inter-site delay intervals;

(g) after ~~step~~ (f) for each pacing mode inter-site delay configuration calculating the average of the ACL

features over all of the occurrences of the configuration;

(h) determining the optimal configuration from among the averages determined in ~~step~~ (g); and

(i) setting the inter-site delays and pacing mode configuration of the pacemaker to the optimal inter-site delays and pacing mode configuration established in ~~step~~ (h).

2(currently amended). ~~The~~ A method ~~of~~ as in claim 1 wherein the ACL feature value is calculated by ~~the steps of~~:

(j) smoothing the array of ACLs;

(k) determining from the smoothed array of ACLs a maximum value and a minimum value in a first predetermined interval measured in beats for each inter-site delay and pacing mode configuration;

(l) determining from the smoothed array a mean value of ACLs in a second predetermined interval measured in beats for each inter-site delay and pacing mode configuration;

(m) computing an absolute value of the difference between said maximum value and said mean value and computing an absolute value of the difference between said minimum value and said mean value;

(n) comparing the absolute value of the difference between the maximum value and the mean value with the absolute value of the difference between the minimum value and the mean value to determine which is the larger; and

(o) setting the ACL feature value to the difference between the maximum value and the mean value when the absolute value of that difference is greater than the absolute value of the difference between the minimum value and the mean value, and setting the ACL feature value to the difference between the minimum value and the mean value when the absolute value of the difference between the maximum value and the mean value is less than or equal to the absolute value of the difference between the minimum value and the mean value.

3(currently amended). A method for optimizing delay intervals between pacing sites and pacing mode configuration of a programmable dual chamber cardiac pacemaker of the type having means for sensing atrial and ventricular depolarization events, including a microprocessor-based controller for using a plurality of sites for selectively stimulating the right, the left or both ventricular chambers with pacing pulses at predetermined delay intervals following detection of atrial depolarization events, the microprocessor-based controller having means for determining

atrial cycle lengths and a memory for storing data in an addressable array, said method comprising ~~the steps of~~:

(a) storing in the memory a listing of pacing mode and inter-site delay configurations, each such configuration specifying ventricular chamber(s) to be stimulated and inter-site delay intervals to be utilized wherein said pacing mode and inter-site delay configurations involve a plurality of sites in at least one cardiac chamber;

(b) pacing the ventricular chamber(s) in accordance with a pacing mode inter-site delay configuration selected randomly from said listing for a first number of beats, N_1, following a second number of intrinsic beats, N_2, sufficient to establish a base line;

(c) repeating ~~step~~ (b) for each pacing mode and inter-site delay configuration contained in the listing;

(d) determining the ACL values between each of the N_1 and N_2 beats resulting from ~~steps~~ (b) and (c) and storing said ACL value in the addressable array in the memory;

(e) repeating ~~steps~~ (b) through (d) a predetermined number of instances, N_3;

(f) smoothing the array of ACLs;

(g) determining for all N_3 instances of each pacing mode and inter-site delay configuration the maximum value of

the smoothed ACLs in a first interval beginning after a change to the first number of beats N_1 and ending after a change to the second number of beats, N_2, and a minimum value of the smoothed ACLs in a second interval beginning a predetermined number of beats prior to a change from the N_2 beats to the N_1 beats and ending with the beat associated with the maximum value;

(h) computing a smoothed ACL feature as the difference between the maximum value and the minimum value;

(i) calculating the mean value of the smoothed ACL features computed in ~~step~~ (h) over the N_3 instances for each pacing mode inter-site delay configuration and determining the configuration yielding the largest mean value;

(j) determining among the N_3 instances associated with the configuration yielding the largest mean value a median value and a maximum value of smoothed ACL features; and

(k) programming the pacemaker to the configuration determined in ~~step~~ (i) when the difference between the ratio of maximum value and the median value is less than a predetermined value.

4(currently amended). ~~The~~ A method ~~of~~ as in claim 3 and when the ratio of maximum value and the median value of smoothed ACL features is greater than or equal to the predetermined threshold

value, repeating ~~steps~~ (i) and (j) after recalculating the mean of the instances of the configuration associated with the largest mean value of smoothed ACL features after removing the instance having the maximum value of smoothed ACL features from the instances.

5(withdrawn). A method of optimizing the inter-site delay and pacing mode configuration of a dual chamber pacemaker of the type having means for sensing atrial depolarization events, means for sensing ventricular depolarization events and means for applying cardiac stimulating pulses selectively to a plurality of sites at locations selected the right, left or both ventricular chambers at predetermined inter-site delay intervals following detection of atrial depolarization events, comprising the steps of:

(a) tracking a patient's intrinsic ventricular depolarization events;

(b) measuring the patient's ventricular cycle length (VCL) between successive ventricular depolarization events over a first predetermined number of heart beats, N_1, and storing the measured VCLs as an array in a memory to establish a baseline value;

(c) changing at least one delay interval and pacing mode configuration by changing, for a second predetermined

number of heart beats, N_2, less than the first predetermined number of heart beats,

(i) one or more inter-site delay intervals of the pacemaker from the baseline value to a different delay interval;

(ii) the sites to which the stimulating pulses are applied;

(d) measuring the patient's VCLs between successive ventricular depolarization events over the second predetermined number of heart beats and storing the measured VCLs in the array in said memory;

(e) calculating and storing a VCL feature value obtained from the patient's ventricular cycle length measured in steps (b) and (d);

(f) repeating steps (a)-(e) in iterative cycles over a range of inter-site delay intervals and ventricular chamber(s) selected for receiving the cardiac stimulating pulses;

(g) after step (f) for each pacing mode inter-site delay configuration calculating the average of the VCL features over all of the occurrences of the configuration;

(h) determining the optimal configuration from among the averages determined in step (g); and

(i) setting the inter-site delay and pacing mode configuration of the pacemaker to the optimal inter-site delay and pacing mode configuration established in step (h).

6(withdrawn). The method of claim 5 wherein the VCL feature value is calculated by the steps of:

(j) smoothing the array of VCLs;

(k) determining from the smoothed array of VCLs a maximum value and a minimum value in a first predetermined interval measured in beats for each inter-site delay and pacing mode configuration;

(l) determining from the smoothed array a mean value of VCLs in a second predetermined interval measured in beats for each inter-site delay and pacing mode configuration;

(m) computing an absolute value of the difference between said maximum value and said mean value and computing an absolute value of the difference between said minimum value and said mean value;

(n) comparing the absolute value of the difference between the maximum value and the mean value with the absolute value of the difference between the minimum value and the mean value to determine which is the larger; and

(o) setting the VCL feature value to the difference between the maximum value and the mean value when the absolute value of that difference is greater than the absolute value of the difference between the minimum value and the mean value, and setting the VCL feature value to the difference between the minimum value and the mean value when the absolute value of the difference between the maximum value and the mean value is less than or equal to the absolute value of the difference between the minimum value and the mean value.

7(withdrawn). A method for optimizing inter-site delay intervals and pacing mode configuration of a programmable, dual-chamber, cardiac pacemaker of the type having means for sensing atrial and ventricular depolarization events, including a microprocessor-based controller using a plurality of pacing sites for selectively stimulating the right, the left or both ventricular chambers with pacing pulses at predetermined inter-site delay intervals following detection of atrial depolarization events, the microprocessor-based controller having means for determining ventricular cycle lengths (VCLs) and a memory for storing data in an addressable array, comprising the steps of:

(a) storing in the memory a listing of pacing mode and inter-site delay configurations, each such configuration specifying ventricular chamber(s) to be

stimulated and an inter-site delay interval to be utilized;

(b) pacing the ventricular chamber(s) in accordance with a pacing mode inter-site delay configuration selected randomly from said listing for a first number of beats, N_1, following a second number of intrinsic beats, N_2, sufficient to establish a baseline;

(c) repeating step (b) for each pacing mode and AV delay configuration contained in the listing;

(d) determining the VCL values between each of the N_1 and N_2 beats resulting from steps (b) and (c) and storing said VCL value in the addressable array in the memory;

(e) repeating steps (b) through (d) a predetermined number of instances, N_3;

(f) smoothing the array of VCLs;

(g) determining for all N_3 instances of each pacing mode and inter-site delay configuration the maximum value of the smoothed VCLs in a first interval beginning after a change to the first number of beats, N_1, and ending after a change to the second number of beats, N_2, and a minimum value of the smoothed VCLs in a second interval beginning a predetermined number of beats prior to a change from the N_2 beats to the N_1 beats and ending with the beat associated with the maximum value;

(h) computing a smoothed VCL feature as the difference between the maximum value and the minimum value;

(i) calculating the mean value of the smoothed VCL features computed in step (h) over the N_3 instances for each pacing mode inter-site delay configuration and determining the configuration yielding the largest mean value;

(j) determining among the N_3 instances associated with the configuration yielding the largest mean value a median value and a maximum value of smoothed VCL feature; and

(k) programming the pacemaker to the configuration determined in step (i) when the difference between the ratio of maximum value and the minimum value is less than a predetermined value.

8(withdrawn). The method of claim 7 and when the ratio of maximum value and the median value of smoothed VCL features is greater than or equal to the predetermined threshold value, repeating steps (i) and (j) after recalculating the mean of the instances of the configuration associated with the largest mean value of smoothed VCL features after removing the instance having the maximum value of smoothed VCL features from the instances.

9(currently amended). A method for optimizing inter-site delay intervals and pacing mode configuration of a programmable, dual-chamber, cardiac pacemaker of the type having means for

sensing atrial and ventricular depolarization events, including a microprocessor-based controller using a plurality of pacing sites for selectively stimulating the right and left ventricular chambers with pacing pulses at predetermined inter-site delay intervals following detection of atrial depolarization events, the microprocessor-based controller having means for determining atrial cycle lengths (ACLs) or ventricular cycle lengths (VCLs) and a memory for storing data in an addressable array, said method comprising ~~the steps of~~:

(a) establishing an upper rate limit and a lower rate limit for pacing and storing these in memory;

(b) establishing a range of allowable delay intervals between pacing the right ventricle and pacing a first site in the left ventricle in relation to said upper rate limit and said lower rate limit; and

(c) making dynamic inter-site delay interval adjustments to optimize the interval based on a linear relationship between the delay interval between adjacent pulses in the right and left ventricles and the VCL or ACL, wherein said inter-site delay interval is adjusted between maximum and minimum values in said range of allowable delay intervals wherein said inter-site delay intervals involve a plurality of sites in at least one cardiac chamber.

10(original). ~~The~~ A method according to claim 9 wherein said adjustments are made on an on-going basis.

11(withdrawn). A method for optimizing atrioventricular delay, comprising:

(a) tracking an intrinsic performance parameter of a patient's heart;

(b) measuring a performance parameter over a first predetermined number of heart beats, N_1, a first set of inter-site delay intervals and storing the measured performance parameter as an array in a memory to establish a baseline value;

(c) changing at least one of one or more inter-site delay intervals and pacing mode configuration for a second predetermined number of heart beats, N_2, less than the first predetermined number of heart beats by charging

 (i) the delay interval of the pacemaker between successive sites from the baseline value to a different delay interval;

(d) measuring the patient's performance parameter between successive atrial depolarization events over the second predetermined number of heart beats and storing the measuring performance parameter in the array in said memory;

(e) calculating and storing an performance parameter feature value obtained from the patient's performance parameter measured in steps (b) and (d);

(f) repeating steps (a)-(e) in iterative cycles over a range of inter-site delay intervals;

(g) after step (e) for each pacing mode inter-site delay configuration calculating the average of the performance parameter features over all of the occurrences of the configuration;

(h) determining the optimal configuration from among the averages determined in step (f); and

(i) setting the inter-site delays and pacing mode configuration of the pacemaker to the optimal inter-site delays and pacing mode configuration established in step (g).

12(withdrawn). A method, as in Claim 11, wherein the performance parameter is selected from the group consisting of ventricular volumes, blood flow velocity, total acoustic noise, and direct measurement of pressure..

13(currently amended). A method of enhancing paced cardiac performance by optimizing the operation of a pacing device, ~~the~~ said method comprising ~~the steps of~~:

(a) measuring a selected cardiac performance parameter indicative of the performance of a patient's heart during

multi-site pacing to establish a baseline using a first pacing device operation setting wherein said multi-site pacing involves a plurality of sites in at least one cardiac chamber;

(b) varying the operation setting;

(c) measuring said parameter during pacing using a changed operation setting; and

(d) determining an optimal pacer device operation setting based on measurements of said parameter at a plurality of settings.

14(currently amended). A method of enhancing paced cardiac performance by optimizing the operation of a pacing device, ~~the~~ said method comprising ~~the steps of~~:

(a) measuring a selected cardiac performance parameter indicative of the performance of a patient's heart during multi-site pacing to establish a baseline using a first setting comprising a first pacing mode and first inter-site delay interval wherein said multi-site pacing involves a plurality of sites in at least one cardiac chamber;

(b) varying the setting by changing an inter-site delay interval or pacing mode;

(c) measuring said parameter during pacing using a changed setting; and

(d) determining an optimal inter-site delay interval and pacing mode configuration based on measurements of said parameter at a plurality of settings.

15(currently amended). The method of claim 14 comprising:

(e) after ~~step~~ (c), for each pacing mode inter-site delay interval and mode configuration used, calculating an average value of the selected parameter of interest;

(f) determining an optimal inter-site delay interval and pacing mode configuration from among the averages determined in ~~step~~ (e); and

(g) setting the inter-site delays and pacing mode configuration of the pacemaker to the optimal inter-site delay pattern and pacing mode configuration established in ~~step~~ (f).

16(previously presented). A method as in claim 14 wherein said selected cardiac performance parameter of interest is selected from the group consisting of atrial cycle length (ACL), ventricle cycle length (VCL), ventricular volumes, blood flow velocity, total acoustic noise and direct measurement of pulse pressure.

17(previously presented). A method as in claim 16 wherein a plurality of selected cardiac performance parameters of interest are employed in obtaining an optimal inter-site delay pattern and pacing mode configuration.

18(currently amended). A method as in claim 16 including ~~the step of~~ performing said optimization method with respect to an exercising patient.

19(currently amended). A method of enhancing one or more aspects of cardiac performance by optimizing pacing mode configuration and/or inter-site delay pattern in a programmable multi-chamber, multi-site pacemaker said method comprising ~~steps of~~:

(a) selecting a cardiac parameter of interest of known relation to an aspect of cardiac performance; and

(b) comparing a plurality of inter-site delay patterns and/or pacing mode configurations in a manner which determines the optimum delay pattern and pacing mode to optimize said parameter and thereby optimize said aspect of cardiac performance, wherein said pacing mode configurations and inter-site delay patterns include a plurality of sites in at least one cardiac chamber.